

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

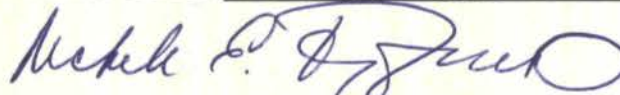
ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date RD Received: 20 December 94 Review Start Date: 4 August 1995

Date EPA Received: 13 December 94 Project Return Date: 13 March 95

Review Completion Date: 4 August 1995

  
Reviewed By: Michele E. Wingfield, Microbiologist

EPA Reg. No. or File Symbol: 10492-4

Product Manager & Team No.: Marion Johnson - 31

Product Name: Isotex -70 Disinfecting Towelettes

Company Name: Palmero Health Care

Submission Purpose: MOU Compliance per PR Notice 94-4

Labeling:

Proposed tamper resistant seal with MOU restrictive label language is acceptable.

On the front panel, remove the paragraph starting with, "Isotex 70 is tuberculocidal against Mycobacterium bovis BCG... fungicidal against Trichophyton mentagrophytes ... in 4 minutes at 20°C." The prominence of these statements on the front panel imply actual contact times however, they are contradictory to the contact time listed in the use directions: 6 minutes for disinfection of pre-cleaned, hard, non-porous inanimate surfaces. Therefore, it is a violation of 40 CFR 156.10.

(5) False or misleading statements.

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser.